



(19)

Europäisches Patentamt
European Patent Office
Office européen des brevets



(11)

EP 0 471 429 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
09.10.1996 Bulletin 1996/41

(51) Int. Cl.⁶: **A61M 25/01**

(21) Application number: **91301318.1**

(22) Date of filing: **20.02.1991**

(54) **Drainage catheter**

Drainagekatheter

Cathéter à drainage

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

(30) Priority: **26.02.1990 US 485269**

(43) Date of publication of application:
19.02.1992 Bulletin 1992/08

(73) Proprietor: **Cook Incorporated**
Bloomington Indiana 47402 (US)

(72) Inventors:
• **Osborne, Thomas Alexander**
Bloomington, Indiana 47402 (US)

• **Parker, Fred Terrance**
Unionville, Indiana 47468 (US)
• **Roll, John Douglas**
Rockford, Illinois 61107 (US)

(74) Representative: **Johnston, Kenneth Graham**
Lucent Technologies (UK) Ltd,
5 Mornington Road
Woodford Green Essex, IG8 OTU (GB)

(56) References cited:
FR-A- 1 460 776 **US-A- 1 207 479**
US-A- 4 643 720 **US-A- 4 898 577**

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

EP 0 471 429 B1

Description

This invention relates to medical devices such as catheters.

Catheters can be used for draining fluids from or for applying fluid(s) to a patient.

One problem with catheters is that they can be easily dislodged and inadvertently draw side ports thereof into abdominal cavities, thereby creating severe infections.

Various catheters have been developed with so-called pigtail loops at their distal ends which both ensures drainage of the cavity and prevents accidental removal therefrom. These loops are controlled by flexible tension members held in place by retention arrangements. US-A-1,207,479, US-A-3,924,677 and US-A-4,643,720 describe three forms of such retention arrangements. US-A-4 643 720 describes the device according to the preamble of claim 1.

Such prior art arrangements are awkward to use and could be inadvertently untied by a patient, with the possibility of the catheter being withdrawn, or partially withdrawn, from the patient.

According to the present invention there is provided a medical device as defined in claim 1.

The lockable sleeve fits over the elongated member, preferably in the region of the proximal end of the elongated member. The proximal end of the elongated member can extend through the sleeve or can be located within the sleeve.

In one embodiment, the drawable means extends through the sleeve and is attached to the proximal end of the sleeve, so that movement of the distal end of the sleeve towards the proximal end of the elongated member applies tension and activates the drawable means. In another embodiment, the drawable means can be attached to the distal end of the sleeve, in which instance the drawable means is activated by movement of the distal end of the sleeve towards the distal end of the elongated means. Clearly the drawable means can be connected to the sleeve at any convenient location.

The sleeve and elongated member can be engaged by a projection on the sleeve engaging a recess in the elongated member, or a recess in a collar about that member. The projection and recess can be interchanged, or each can have a recess with a co-operating ring which can lock into both recesses upon engagement. Clearly, other alternative locking mechanisms could be employed.

The advantages of the embodiments is that by simply moving the sleeve, the distal end of the elongated member is drawn into the pigtail configuration without the physician having to individually pull, cut or tie the free end of the flexible tension member.

The proximal end of the sleeve is connected to a fluid collection system.

Brief description of the drawings

FIG.1 is a partially-sectioned view of a lockable sleeve drainage catheter of the present invention; FIG.2 depicts a partially-sectioned view of the catheter of FIG.1 inserted in the bladder of a patient; FIG.3 depicts a partially-sectioned view of the catheter of FIG.2 in a locked position; FIG.4 depicts an alternative embodiment of the distal end of the catheter for use in the biliary system of a patient; and FIG.5 depicts a second alternative embodiment of the distal end of the catheter for use as a gastrostomy feeding tube.

FIG.1 shows catheter 101 in an unlocked position prior to percutaneous insertion into a patient.

Depicted in FIG.2 is catheter 101 with stiffening cannula 126 inserted into bladder 102 over wire guide 103. Before insertion of catheter 101, a thinwall needle with a stylet inserted therein (not shown) is percutaneously inserted through abdominal wall 130 into the bladder using a well-known technique. The stylet is removed, and the wire guide is inserted through the needle into the bladder. The needle is then removed with the wire guide left in place. A dilator is commonly used over the wire guide to increase the size of the puncture site. Drainage catheter 101 with a stiffening cannula inserted therein is then inserted over the wire guide into bladder 102 as shown.

As shown in FIGS.1 and 2, catheter 101 includes an elongated member 104 and a lockable sleeve 110, both formed from flexible plastic material tubes having different diameters. Flexible member 104 has a tapered distal end 105, a flared proximal end 106, and a hollow longitudinal passageway 107 therebetween. Distal end 105 is preformed into a predetermined configuration such as a well-known pigtail. A plurality of side ports 108 are formed through the wall of the elongated member about the distal end thereof for fluid such as urine to enter and drain through passageway 107. Passageway 107 also forms an opening 109 at the very distal end of the elongated member. Opening 109 permits the insertion of the catheter into a patient over the wire guide and also allows further drainage of fluid into passageway 107. However, a stiffening cannula is normally inserted through passageway 107 of the catheter to straighten the preformed distal end for percutaneous insertion over the wire guide into the bladder. When the catheter has been inserted in the bladder, the stiffening cannula and wire guide are then removed from passageway 107.

Similarly, lockable sleeve 110 has a tapered distal end 111, a proximal end 112, and a hollow longitudinal passageway 113 therebetween. By way of example, elongated member 104 is a 10.2 French polyurethane material tube approximately 32cm. in length, whereas lockable sleeve 110 is a 20 French polyurethane material tube approximately 6.5cm. in length. As shown, flared proximal end 106 of the elongated member tube

and locking collar 114 affixed thereabout are positioned within sleeve passageway 113 and are longitudinally moveable therein.

The generally cylindrically-shaped locking collar includes two truncated cones 127 and 128 with beveled surfaces 115 and 116 facing the opposite ends of the collar. Base surfaces 117 and 118 of respective cones 127 and 128 and the outside surface 119 of the collar therebetween form an annular recess, such as a groove or channel, in the collar. Lockable sleeve 110 is longitudinally moveable over locking collar 114.

Distal end 111 of the lockable sleeve includes a projection 120, such as an annular ridge or step, which extends into passageway 113 to engage the annular recess of locking collar 114. As shown, annular step 120 at the tapered distal end 111 of the sleeve is sized to snap fit into the annular recess of collar 114 when the distal end of the sleeve is longitudinally moved over beveled surface 115. As a result, annular step 120 snaps into the annular recess of the collar. The minimum dimension or diameter of passageway 113 through annular step 120 is less than the maximum dimension or diameter of outside surface 119 of the collar in the annular recess. The two dimensions are sized to form a tight fit between the annular step and recess when interconnected, which prevents the passage of fluid through the interconnection. Beveled surface 116 of the collar and flared distal end 106 of the tube further prevent the passage of fluid through the interconnection.

The drainage catheter further includes flexible tension member 121 that passes through passageways 107 and 113. Draw ports 122 and 123 are formed through the wall of the elongated member tube near drain ports 108. The flexible tension member passes from within passageway 107 through draw port 122 to the exterior of the elongated member and back into interior passageway 107 through draw port 123. The flexible tension member forms a loop through the draw ports, which is drawable to position the distal end of the elongated member tube into the desired pigtail configuration. The ends of the flexible tension member are secured to the sleeve and preferably to proximal end 112 of the lockable sleeve between the wall of the sleeve and the outside barbed surface of a well-known Luer lock connector 124. The flexible tension member, such as commercially available 4-0 Tevdek suture, is further secured between the two surfaces using, for example, Lockite 401 sealing compound.

When distal end 105 of elongated member tube 104 is fully extended for insertion into the bladder, lockable sleeve 110 is in a fully forward and unlocked position with the flared proximal end 106 of the tube positioned next to connector 124. Commonly, the Luer lock connector is formed with a taper at the distal end thereof. As a result, the flared proximal end 106 receives the tapered end of the Luer lock connector. The flared end fits against the wall of the sleeve to prevent the passage of fluid and flexible tension member therebetween.

Depicted in FIG.3 is a partially-sectioned view of drainage catheter 101 with sleeve 110 in a fully drawn and locked position and distal end 105 positioned in the pigtail configuration. The pigtail configuration at the distal end of elongated member tube 104 acts as a retention device to prevent the catheter from being removed from the bladder. In the locked position, the sleeve has been longitudinally moved along the proximal end of the elongated member tube to engage annular step 120 with outside surface 119 in annular recess of collar 114. When the sleeve is pulled, and the member 104 is held fixed, the flexible tension member 121 is drawn through and out of elongated member passageway 107 to close the loop between draw ports 122 and 123, thereby positioning the distal end of the elongated member tube into the pigtail configuration. Retention disk 129 is applied to the outside surface of abdominal wall 130 around the elongated member with tie 125 to more securely position the drainage catheter in the patient. Retention disk 129 is commercially available from a number of sources such as Cook Incorporated, Bloomington, Indiana. Flexible elongated member tube 104 may also be bent to run alongside the patient's body using a 90° retention disk also available from Cook Incorporated.

Depicted in FIG.4 is an alternative embodiment of the distal end of the drainage catheter. In this particular embodiment, distal end 401 of elongated member 402 of the catheter has been preformed into a well-known configuration for retaining the distal end in the biliary system of a patient. A plurality of drainage ports 403 and 404 have been formed about the distal end and the main body of elongated member 402, respectively.

Depicted in FIG.5 is a second alternative embodiment of the distal end of the elongated member portion of the drainage catheter. In particular, distal end 501 of elongated member tube 502 has been formed into a pigtail configuration with the distal end extending from pigtail curl 503. Such a configuration is suitable for use as a percutaneously inserted gastrostomy feeding tube.

The distal end of the catheter may be preformed into any desired configuration for positioning and retaining the distal end of the catheter in any part of a patient's body. Furthermore, the lockable sleeve of the drainage catheter may be designed with an O-ring seal or the like for being locked into associated recesses in the lockable collar and/or the lockable sleeve, and for preventing fluid from passing through the joined or locked interconnection of the sleeve and elongated member. Similarly, a single finger-like projection may extend into a recess formed in the proximal end of the elongated member tube. However, the illustrative embodiment illustrates a drainage catheter which is easily manipulated by the physician without having to tie the flexible tension member. Once in the locked position, the catheter maintains a closed system for which fluid may be drained from the patient. Furthermore, one end of the flexible tension member may be attached in any one of a number of well-known ways to the distal end of the elongated member and drawable through

one or more draw ports for positioning the distal end and in the desired position.

Claims

1. A medical device comprising an elongated member (104) having a distal end (105), a proximal end (106), and a passageway (107) extending therebetween, at least the distal end being for insertion into a patient; and means (121) extending between the said distal and proximal ends and drawable to reconfigure the distal end into a desired configuration; the device further comprising an elongated sleeve (110) having distal and proximal ends with a passageway (113) therebetween, characterised in that the sleeve is positioned about and longitudinally moveable with respect to and adjacent to the proximal end of the longitudinal member; in that the drawable means is attached to the sleeve; and in that the longitudinal member within the sleeve and the interior of the sleeve have co-operating parts (119,120) associated therewith for engaging the sleeve and the longitudinal member together when moved relative to one another to an engaging or interlocking position, the relative movement of the distal end of the sleeve towards the proximal end of the elongated member causing the drawable means to reconfigure the distal end of the elongated member into the desired configuration.
2. A device according to claim 1, characterised in that means (124) are provided for clamping the drawable member relative to the proximal end of the sleeve.
3. A device according to claim 1 or 2, characterised in that the co-operating parts comprise an annular ridge (120) on the interior surface of the sleeve, and a co-operating recess (119) associated with the exterior surface of the longitudinal member, the relative movement required to bring the ridge and the recess into co-operative engagement serving to provide the required movement of the drawable means.
4. A device according to claim 3, characterised in that a collar (114) is provided about and fixed adjacent to the proximal end of the elongated member, in that the recess (119) is in the outer surface of the collar, the recess being sized to tightly receive the said ridge.
5. A device according to claim 4, characterised in that the opening of the ridge has a dimension less than a maximum outside dimension of the collar in the annular channel.
6. A device according to any one preceding claim, characterised in that the elongated member com-

prises, adjacent to the distal end, a plurality of parts (108) for supplying fluid to, or for draining fluid from, a patient.

7. A device according to any one preceding claim, characterised in that the drawing means include a flexible tension member extending along the elongated member to at least one draw port adjacent to the distal end of the member.
8. A device according to any one preceding claim, characterised in that when the sleeve and elongated member are interlocked, the co-operating parts provide a seal to prevent leakage of fluid between the elongated member and the sleeve.

Patentansprüche

1. Medizinische Vorrichtung, die ein längliches Glied (104) mit einem distalen Ende (105), einem proximalen Ende (106) und einem zwischen diesen beiden Enden verlaufenden Durchgang (107), wobei mindestens das distale Ende zur Einführung in einen Patienten bestimmt ist; sowie ein sich zwischen diesem distalen und proximalen Ende erstreckendes und zur Rekonfiguration des distalen Endes in eine gewünschte Konfiguration ziehbares Mittel (121) umfaßt, wobei die Vorrichtung weiterhin eine längliche Hülse (110) mit einem distalen und einem proximalen Ende und einem dazwischen verlaufenden Durchgang (113) umfaßt, dadurch gekennzeichnet, daß die Hülse um das proximale Ende des länglichen Gliedes herum, entlang diesem beweglich und neben diesem angeordnet ist, daß das ziehbare Mittel an der Hülse befestigt ist und daß das längliche Glied in der Hülse und das Innere der Hülse zusammenwirkende Teile (119, 120) aufweisen, die damit zum Eingriff in die Hülse und mit dem länglichen Glied bei einer Relativbewegung zueinander in eine Eingriffs- oder Verbindungsstellung verbunden sind, wobei die Relativbewegung des distalen Endes der Hülse zum proximalen Ende des länglichen Gliedes dazu führt, daß das ziehbare Mittel das distale Ende des länglichen Gliedes zu der gewünschten Konfiguration umformt.
2. Vorrichtung gemäß Anspruch 1, dadurch gekennzeichnet, daß Mittel (124) zum Einklemmen des ziehbaren Mittels relativ zum proximalen Ende der Hülse vorgesehen sind.
3. Vorrichtung gemäß Anspruch 1 oder 2, dadurch gekennzeichnet, daß die zusammenwirkenden Teile einen ringförmigen Wulst (120) auf der Innenfläche der Hülse und eine damit zusammenwirkende, mit der Außenfläche des länglichen Gliedes verbundene Nische (119) aufweisen, wobei die zum zusammenwirkenden Eingriff des Wulstes mit

der Nische erforderliche Relativbewegung dazu dient, für die erforderliche Bewegung des ziehbaren Mittels zu sorgen.

4. Vorrichtung nach Anspruch 3, dadurch gekennzeichnet, daß ein Kragen (114) um das proximale Ende des länglichen Gliedes angebracht und neben diesem befestigt ist, und daß die Nische (119) sich in der Außenfläche des Kragens befindet, wobei die Nische eine solche Größe aufweist, daß sie jenen Wulst eng aufnehmen kann. 5 10
5. Vorrichtung gemäß Anspruch 4, dadurch gekennzeichnet, daß die Öffnung des Wulstes eine Dimension aufweist, die kleiner ist als eine maximale Außenabmessung des Kragens im ringförmigen Kanal. 15
6. Vorrichtung gemäß einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß das längliche Glied neben dem distalen Ende eine Vielzahl von Teilen (108) zur Flüssigkeitsversorgung eines Patienten bzw. zur Flüssigkeitsdrainage aus einem Patienten aufweist. 20
7. Vorrichtung gemäß einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die ziehbaren Mittel ein sich entlang dem länglichen Glied zu mindestens einer Ziehöffnung neben dem distalen Ende des Gliedes erstreckendes flexibles Zugmittel aufweisen. 25 30
8. Vorrichtung gemäß einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die zusammenwirkenden Teile bei Verbindung der Hülse mit dem länglichen Glied für eine Dichtung zur Verhinderung des Auslaufens von Flüssigkeit zwischen dem länglichen Glied und der Hülse sorgen. 35 40

Revendications

1. Dispositif médical comprenant un organe allongé (104) ayant une extrémité distale (105), une extrémité proximale (106), et un passage (107) s'étendant entre elles, l'extrémité distale au moins étant destinée à être insérée dans un patient; et un moyen (121) s'étendant entre lesdites extrémités distale et proximale et étirable pour reconfigurer l'extrémité distale en une configuration désirée; le dispositif comprenant en outre un manchon allongé (110) ayant des extrémités distale et proximale avec un passage (113) entre elles, caractérisé en ce que le manchon est placé autour de l'extrémité proximale de l'organe longitudinal et est longitudinalement mobile par rapport à celui-ci et adjacent à celui-ci; en ce que le moyen étirable est attaché au manchon; et en ce que l'organe longitudinal à l'intérieur du manchon et l'intérieur du manchon ont des parties coopérantes (119, 120) associées à ceux-ci pour engager le manchon et l'organe longitudinal ensemble lorsqu'elles sont déplacées l'une par rapport à l'autre dans une position d'engagement ou de verrouillage, le mouvement relatif de l'extrémité distale du manchon vers l'extrémité proximale de l'organe allongé contraignant le moyen étirable à reconfigurer l'extrémité distale de l'organe allongé dans la configuration désirée. 5
2. Dispositif selon la revendication 1, caractérisé en ce qu'un moyen (124) est prévu pour bloquer l'organe étirable par rapport à l'extrémité proximale du manchon. 10
3. Dispositif selon la revendication 1 ou 2, caractérisé en ce que les parties coopérantes comprennent une saillie annulaire (120) sur la face intérieure du manchon, et une gorge (119) coopérante associée à la face extérieure de l'organe longitudinal, le mouvement relatif requis pour mettre la saillie et la gorge en engagement coopérant servant à fournir le mouvement requis du moyen étirable. 15
4. Dispositif selon la revendication 3, caractérisé en ce qu'un collier (114) est prévu autour de l'extrémité proximale de l'organe allongé et fixé à côté d'elle, en ce que la gorge (119) est dans la face extérieure du collier, la gorge étant dimensionnée pour recevoir étroitement ladite saillie. 20 25 30
5. Dispositif selon la revendication 4, caractérisé en ce que l'ouverture de la saillie a une dimension inférieure à une dimension extérieure maximale du collier dans le canal annulaire. 35
6. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce que l'organe allongé comprend une pluralité de parties (108), adjacentes à l'extrémité distale, pour fournir du fluide à un patient, ou pour drainer celui-ci. 40
7. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce que le moyen d'étirage comporte un organe de tension flexible s'étendant le long de l'organe allongé jusqu'à au moins un orifice d'étirage adjacent à l'extrémité distale de l'organe. 45
8. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce que, lorsque le manchon et l'organe allongé sont verrouillés, les parties coopérantes fournissent une fonction étanche pour empêcher les fuites de fluide entre l'organe allongé et le manchon. 50 55

EP 0 471 429 B1

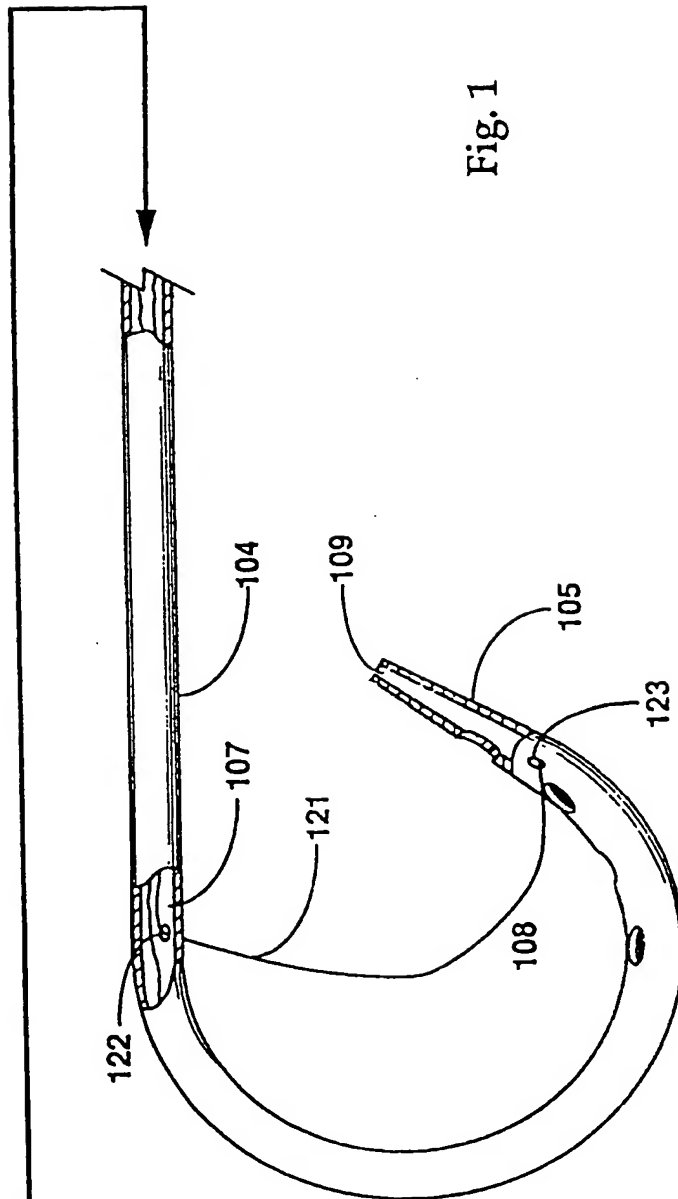
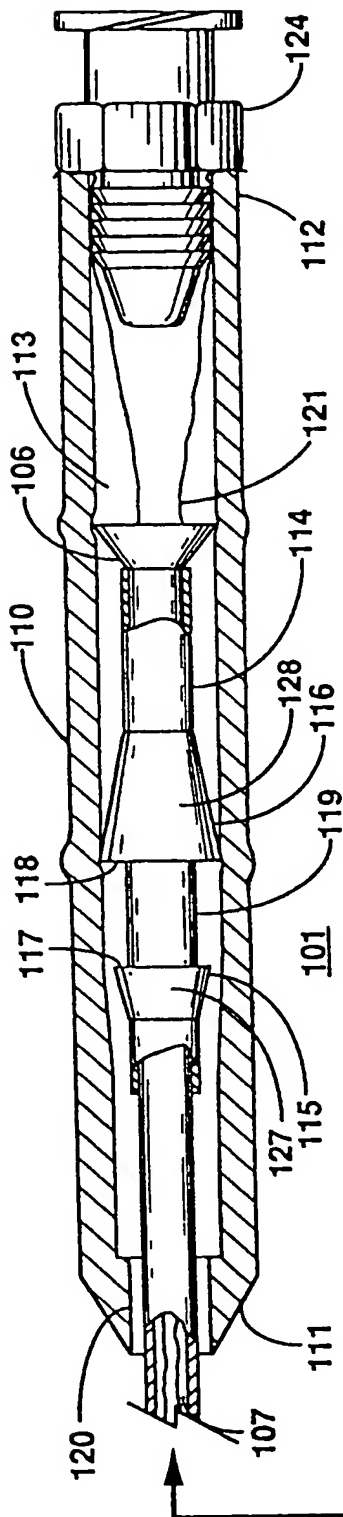


Fig. 1

EP 0 471 429 B1

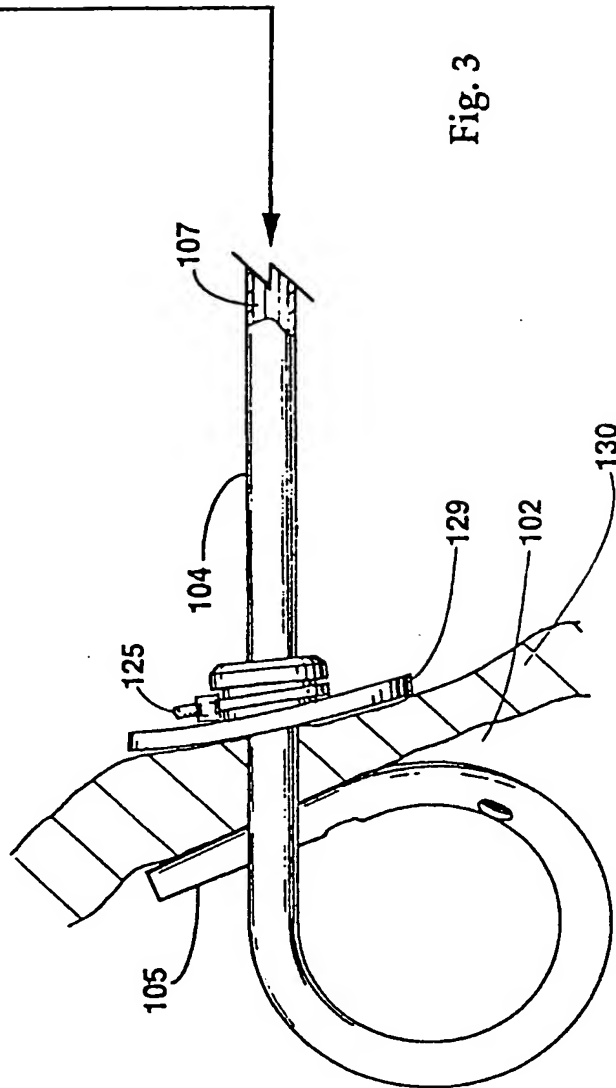
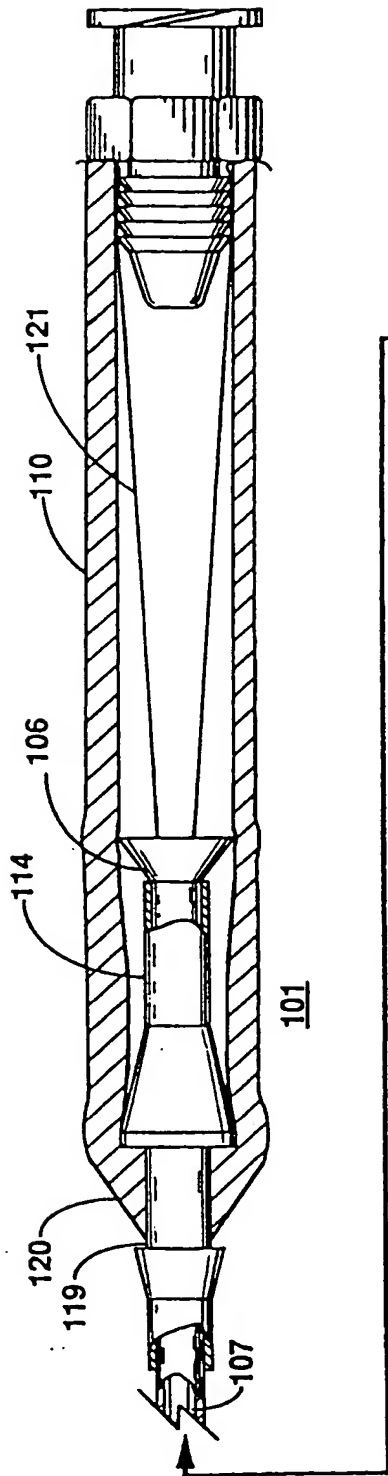


Fig. 3

EP 0 471 429 B1

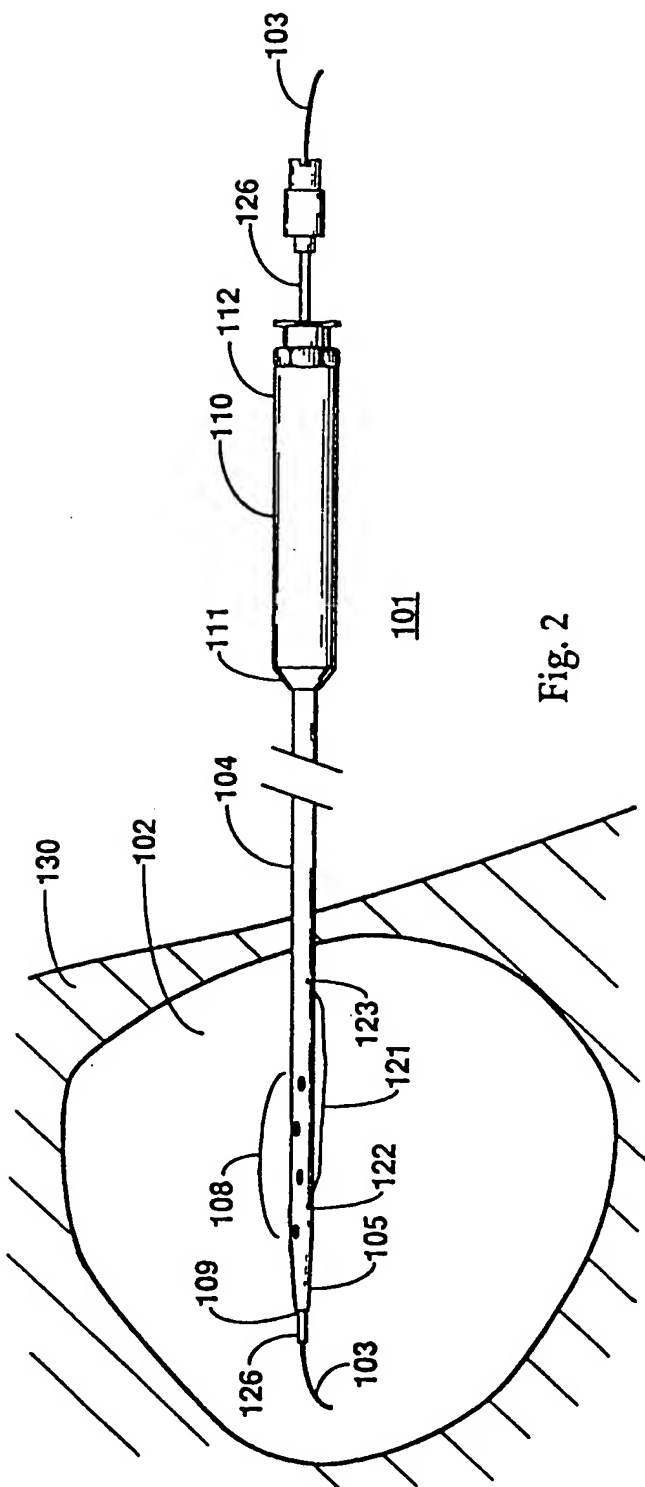


Fig. 2

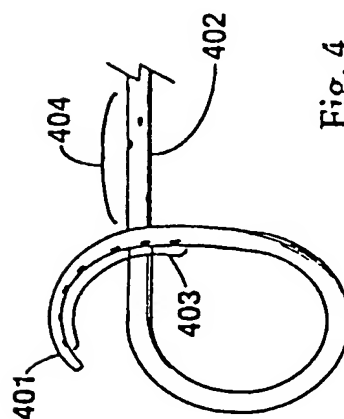


Fig. 4

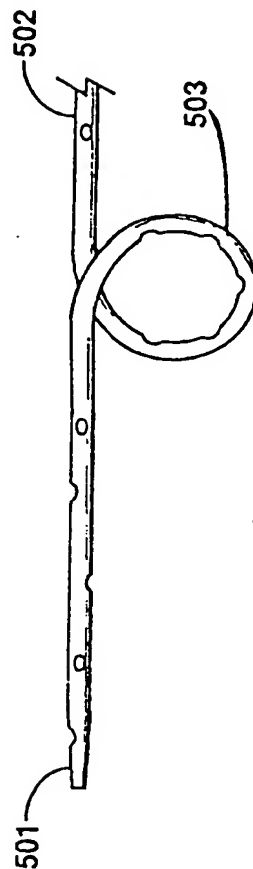


Fig. 5